

INTERNATIONAL APPLICATION PUBLISHED UNDER 1

WO 9607377A1

(51) International Patent Classification ⁶:

A61F 9/00

A1

(11) International Publication Number: WO 96/07377

(43) International Publication Date: 14 March 1996 (14.03.96)

(21) International Application Number: PCT/AU95/00558

(22) International Filing Date: 30 August 1995 (30.08.95)

(30) Priority Data:

PM 7844 2 September 1994 (02.09.94) AU 08/486,861 7 June 1995 (07.06.95) US

(60) Parent Application or Grant

(63) Related by Continuation

US Filed on 08/486,861 (CIP) 7 June 1995 (07.06.95)

(71) Applicant (for all designated States except US): OVERSBY PTY. LTD. [AU/AU]; Level 1, 10 Kings Park Road, West Perth, W.A. 6005 (AU).

(72) Inventor; and

(75) Inventor/Applicant (for US only): BARRETT, Graham, David [AU/AU]; 56 Dampier Avenue, City Beach, W.A. 6015 (AU).

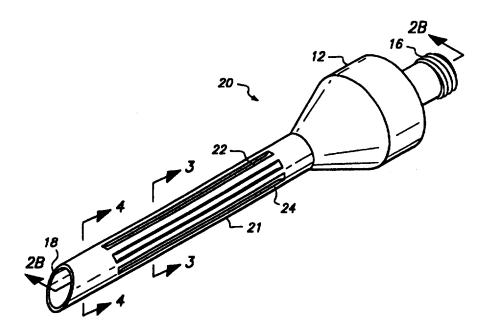
(74) Agent: LORD, Kelvin, Ernest; 4 Douro Place, West Perth, W.A. 6005 (AU).

(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TT, UA, UG, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ, UG).

Published

With international search report.

(54) Title: GROOVED PHACO-EMULSIFICATION NEEDLE



(57) Abstract

A phase-emulsification needle (20) is provided for use with a plastic or elastomeric sleeve (17), the needle having a mid-region portion defining a plurality of outwardly extending projections (24) forming longitudinally-oriented grooves (30) that provide adequate irrigant flow rates to the anterior chamber of the eye, even when the entry wound compresses the sleeve (17) against the outer surface of the needle (20), thereby reducing the risk of collapse of the anterior chamber due to inadequate irrigant flow and reducing the risk of excessive heat transmission to the entry wound.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgystan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic	SD	Sudan
CG	Congo		of Korea	SE	Sweden
CH	Switzerland	KR	Republic of Korea	SI	Slovenia
CI	Côte d'Ivoire	KZ	Kazakhstan	SK	Slovakia
CM	Cameroon	LI	Liechtenstein	SN	Senegal
CN	China	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TG	Togo
CZ	Czech Republic	LV	Latvia	TJ	Tajikistan
DE	Germany	MC	Monaco	TT	Trinidad and Tobago
DK	Denmark	MD	Republic of Moldova	UA	Ukraine
ES	Spain	MG	Madagascar	US	United States of America
FI	Finland	ML	Mali	UZ	Uzbekistan
FR	France	MN	Mongolia	VN	Viet Nam
GA	Gabon		-		

5

GROOVED PHACO-EMULSIFICATION NEEDLE

Field Of The Invention

The present invention relates generally to phaco-emulsification needles and more particularly to needles that provide improved irrigation and reduced risk of corneal or scleral tissue damage.

Background Of The Invention

10 Occurrence of the disease known as cataracts, in which the lens of the eye becomes clouded, is common, and can lead to blindness. It has become accepted practice to alleviate this condition by surgically removing the cataract-effected lens and 15 replacing it by an artificial intraocular lens.

The cataract-effected lens is usually removed by manual extraction or phaco-emulsification. Manual extraction requires expression of the nucleus of the lens through a wound of about 12 mm in length.

The technique known as phaco-emulsification, as described, for example, in U.S. Patent 3,589,363, enables removal of a cataract-effected lens through a much smaller incision of about 2.5-4 mm, for example, 3.2 mm. This is accomplished using high frequency ultrasound energy, typically of 40 kHz frequency, that is transmitted by a phaco-emulsification needle to fragment or emulsify the nucleus of the cataract-effected lens. Once fragmented or emulsified, the nuclear material is aspirated through a lumen of the phaco-emulsification needle.

During aspiration of the fragmented nucleus, a simultaneous flow of liquid into the eye is provided around the needle via a soft plastic or elastomeric sleeve concentrically disposed over the needle to form

an annulus. This flow of liquid into the eye is essential to prevent collapse of the anterior chamber of the eye while the fragmented or emulsified nucleus is aspirated via the phaco-emulsification needle.

5 Also, the inflowing liquid serves to cool the needle, thus reducing heat generated by the ultrasonic vibration of the needle. If this heat were instead permitted to be transmitted to the entry wound of the eye, thermal damage of the cornea or scleral tissue could result.

One difficulty encountered in practicing the phaco-emulsification technique is the necessity of maintaining a low-leakage seal between the entry wound in the eye and the sleeve surrounding the phaco-emulsification needle. If the wound entrance is too small, the sleeve may be compressed against the needle, thereby restricting the flow of irrigant into the anterior chamber and allowing frictional heat to be transmitted to the wound.

avoid compression of the sleeve, unacceptably high leakage may occur around the sleeve, for example, at rates of 25 cc/minute. The liquid lost by leakage must be replaced by liquid inflow through the annulus between the plastic sleeve and the needle, thus reducing the safety margin in maintaining a constant anterior chamber volume. Accordingly, to avoid collapse of the anterior chamber, liquid inflow through the annulus should never be less than total liquid outflow via the phaco-emulsification lumen and leakage around the sleeve.

In response to these concerns, a number of techniques have been developed which attempt to reduce leakage from the wound by improving the seal between the wound and the sleeve, while avoiding heat transmission to the wound.

- 3 -

A first technique uses a rigid plastic sleeve made from a material such as polysulphone rather than a softer silicone material, because polysulphone resists compression by the wound. Another technique, described 5 in U.S. Patent 5,282,786, incorporates a rigid plastic or metal sleeve disposed on the outer circumference of a softer silicon sleeve, so that the rigid plastic contacts the entry wound. These techniques, however, have the drawback that they increase wound distortion and tend to enlarge the wound during the procedure, thus enhancing leakage.

10

15

20

25

A second technique, described for example in U.S. Patents 5,286,256 and 5,354,265, employs a rigid plastic or metal intermediate sleeve inserted in the annulus between the conventional outer soft silicone sleeve and the phaco-emulsification needle. intermediate sleeve is permitted to "float" on the exterior of the phaco-emulsification needle, and the needle may have a reduced outer diameter in a middle region to limit longitudinal travel of the intermediate sleeve. The reduced middle region of the needle permits a small incision while maintaining fluid flow around the phaco-emulsification needle. However, such benefits are believed to be more than offset by the increase in the overall diameter of the apparatus to accommodate the intermediate sleeve and the overall reduction in the irrigation cross-sectional flow area caused by the presence of the intermediate sleeve.

A yet third technique attempting to solve the 30 problems of fluid leakage from the entry wound and heat transmission is described in U.S. Patents 4,634,420, 4,643,717, 4,808,154 and 5,242,385. The sleeves described in these patents each include a plurality of inwardly extending ribs that serve to reinforce the sleeve against compression, to limit contact between the sleeve and the phaco-emulsification needle, and to

PCT/AU95/00558 WO 96/07377

provide flow channels in the event that the sleeve is compressed against the needle. All of these designs share the common drawback that the ribs enhance the rigidity of the sleeve, and thus pose a risk of 5 transmitting more frictional heat to the entry wound. In addition, all of these designs require a larger entry wound to accommodate the added dimension of the ribs. Moreover, if the ribs are formed of silicone or other soft plastic or elastomeric material, it is expected that the compressive loads transmitted to such 10 sleeves from the entry wound may compress the ribs to an extent that unacceptably low flow rates might still occur.

In view of the foregoing, it would be desirable to provide a phaco-emulsification needle that overcomes the drawbacks of previously known needle and sleeve arrangements by permitting the use of a small wound size, and that reduces the risk of restriction of fluid flow around the needle.

15

20

30

35

It further would be desirable to provide a phaco-emulsification needle that provides reduced contact area between the needle and the sleeve, thus reducing the transmission of heat to adjacent tissue, with concomitant reduction in the risk of tissue 25 damage.

It would be still further desirable to provide a phaco-emulsification needle that ensures adequate irrigant flow even in those cases where the sleeve is compressed against the exterior of the needle.

It would be yet further desirable to provide a device for use with a phaco-emulsification needle that would improve fluid flow and reduce heat transmission in those cases where the sleeve is subjected to high compressive loading by the entry wound.

- 5 -

Summary Of The Invention

30

In view of the foregoing, it is an object of the present invention to provide a phaco-emulsification needle that overcomes the drawbacks of previously known needle and sleeve arrangements by permitting the use of a small wound size, and that reduces the risk of restriction of fluid flow around the needle.

It is a further object of the invention to

10 provide a phaco-emulsification needle that provides
reduced contact area between the needle and the sleeve,
thus reducing the transmission of heat to adjacent
tissue, with concomitant reduction in the risk of
tissue damage.

It is still a further object of the present invention to provide a phaco-emulsification needle that ensures adequate irrigant flow even in those cases where the sleeve is compressed against the exterior of the needle.

It is yet another object of this invention to provide a device for use with a phaco-emulsification needle that improves fluid flow and reduces heat transmission in those cases where the sleeve is subjected to high compressive loading by the entry wound.

These and other objects of the invention are accomplished in accordance with the principles of the present invention by providing a phaco-emulsification needle comprising a shaft having an axially extending lumen for removal of material from an eye, and at least in a middle region of the needle, one or more axially extending channels or grooves disposed externally of the lumen for supplying fluid to the eye during aspiration.

With the phaco-emulsification needle of the present invention, even if a soft plastic or elastomeric sleeve is compressed against the needle, the channels or grooves permit continued fluid flow while reducing the contact area between the sleeve and needle, thereby reducing the risk of thermal damage to the entry wound.

In a second embodiment of the present invention, a sleeve having a plurality of outwardly extending projections is provided that may be disposed on the exterior surface of a phaco-emulsification needle. The sleeve of the second embodiment may be disposed in a reduced circumference mid-region of the needle to provide benefits similar to those of the first embodiment described hereinabove.

Further features of the invention, its nature and various advantages will be more apparent from the accompanying drawings and the following detailed description of the preferred embodiments.

20 Brief Description Of The Drawings

FIG. 1 is a side elevation of a previously known phaco-emulsification needle;

FIG. 2A is a perspective view of a phacoemulsification needle constructed in accordance with 25 the present invention;

FIG. 2B is a sectional view taken along line 2B--2B of the phaco-emulsification needle of FIG. 2A, showing the needle disposed within a sleeve;

FIG. 3 is an enlarged cross-sectional view 30 taken along the line 3-3 of FIG. 2A;

FIG. 4 is an enlarged cross-sectional view taken along the line 4-4 of FIG. 2A;

FIGS. 5A and 5B are, respectively, perspective and sectional views of an alternative embodiment of the needle of FIG. 2A;

10

25

30

35

an unacceptable extent.

FIG. 6 is a perspective view of another alternative embodiment of the phaco-emulsification needle of FIG. 2A;

FIGS. 7A through 7D are alternative designs for tip 18 of any of the phaco-emulsification needles of the present invention;

FIG. 8A is a perspective view of a ribbed sleeve and phaco-emulsification needle in accordance with another alternative embodiment of the present invention; and

FIG. 8B is a sectional view taken along line 8B--8B of the phaco-emulsification needle of FIG. 8A, showing the needle disposed within a sleeve.

Detailed Description Of The Preferred Embodiments

- Referring to FIG. 1, a previously known phaco-emulsification needle 10 is shown comprising hub 12 and hollow shaft 14 extending from hub 12. A threaded portion 16 extends away from hub 12 on the proximal portion of shaft 14, as is conventional.
- 20 Shaft 14 terminates in tip 18 at the distal end (i.e., remote from hub 12).

Needle 10 contains a central axially extending lumen 13 through which material can be drawn from an eye using known techniques, as described hereinabove. Sleeve 17, which typically comprises a soft silicone material, is disposed over needle 10 to form an annulus 19 through which liquid can be supplied to the anterior chamber of the eye during aspiration. As further described hereinabove, sleeve 17 can be compressed by the eye, and in particular, the portion surrounding the entry wound, to reduce liquid flow to

Referring now to FIGS. 2A and 2B, phacoemulsification needle 20 constructed in accordance with the present invention is described, in which like numbers denote like parts. As will of course be understood by one of skill in the art, FIGS. 2A and 2B are not drawn to scale, but are provided merely for illustration. Needle 20, which is typically made of titanium, comprises hub 12, lumen 13, threaded portion 16, tip 18 and tubular portion 21 located in mid-region 25 between tip 18 and hub 12.

Referring now also to FIG. 3, tubular portion 21 illustratively comprises hollow reduced—
10 circumference cylindrical member 22 having a plurality of equispaced rib-like projections or flanges 24 extending radially outwardly from the outer surface of member 22. As shown in FIG. 2B, if projections 24 in mid-region 25 are alternatively viewed from the perspective of the outer diameter of the adjacent proximal and distal regions, the interstices between adjacent projections 24 appear as longitudinally—oriented channels or grooves 30 in the outer surface of needle 20.

Projections 24 on reduced-circumference 20 cylindrical member 22 may have their outer surfaces formed flush with the outer surface of needle 20 in the regions proximal and distal to mid-region 25 (as in FIG. 2B), or extend slightly below or beyond the outer 25 surface of needle 20 in the adjacent proximal and distal regions. To accommodate projections 24 (and thus grooves 30), lumen 13 may have a reduced diameter in central region 25, as can be seen by comparison of FIGS. 3 and 4. Projections 24 and reducedcircumference cylindrical member 22 may be disposed only in central or mid-region 25 of needle 20, which is the region typically subjected to compressive loading by the tissue surrounding the entry wound, or may alternatively extend along the entire outer surface of 35 needle 20 to tip 18.

WO 96/07377

Disposed about and spaced from tubular portion 21 is sleeve 17, which may be formed of soft plastic or elastomeric material, for example, silicone. When sleeve tube 17 is subjected to a compressive load and contacts needle 20, adjacent projections 24, together with the intervening portion of reduced-circumference cylindrical member 22 and the inner surface of sleeve 17, form channels or grooves 30 which extend axially along needle 20.

Accordingly, if needle 20 comes under pressure along its mid-region 25 during a procedure of removing a cataract-effected lens, reduction in the cross-sectional areas of the channels 30 is inhibited by the presence of projections 24. Liquid flow through the sleeve 17 via channels 30 therefore can be maintained at a satisfactory 14 yel to replenish liquid removed by aspiration in the anterior chamber of the eye.

Moreover, no special external sleeves are
required to ensure adequate irrigation using needle 20.
Thus, sealing between the sleeve 17 and entry wound may
be accomplished with a previously known sleeve 17 as
described with respect to FIG. 1, while maintaining the
required wound size in the desired 2.5 - 3.2 mm range.

Tubular portion 21 may be of a variety of shapes in cross-section, including circular and elliptical, and may have an outer circumference that is smaller than, the same as, or larger than the circumference of the adjacent proximal and distal portions of needle 20. In addition, central lumen 13 of needle 20 may have a single diameter over its entire length, or may be formed having a reduced diameter in the mid-region of tubular portion 21.

Likewise, projections 24 (and grooves 30) may 35 be greater or fewer in number than shown in the accompanying figures, and form greater or lesser

30

portions of the outer circumference of central portion 25 than shown in the accompanying figures, which are to be understood as exemplary only. Moreover, projections 24 need not be spaced equidistant apart around the circumference of tubular portion 24, but may instead be concentrated on the upper and lower portions of needle 20, which are most likely to experience compressive loads.

Referring now to FIGS. 5 and 6, alternative embodiments of the phaco-emulsification needle of the 10 present invention are shown, again in which like numbers denote like parts. In FIG. 5A, needle 20' has longitudinally-oriented projections 24 that spiral around the circumference of cylindrical member 22, 15 thereby creating spiral channels. As illustrated in FIG. 5B, projections 24 may be formed or machined to create hollow channels 26 that communicate with lumen 13, thereby increasing the flow area through the midportion of the needle. As will of course be understood 20 by one of skill in the art, the rib-like projections 24 of any of the embodiments of FIGS. 2-5 may advantageously include hollow channels 26. addition, the channels may be disposed either in the mid-portion of the needle, or extend for the length of 25 the entire inner surface of the needle.

In FIG. 6, projections 24 on needle 20 are formed as individual longitudinally-oriented diamond-shaped islands extending outward from the outer circumference of cylindrical member 22, for example, by cross-cutting reverse-spiral grooves in the needle of FIG. 5. As will of course be understood by one of skill in the art, grooves 30 may be disposed in a needles 20' and 20'' by rotating the needle as the grooves 30 are being formed.

In a preferred embodiment of the needle of FIGS. 2-6, projections 24 and cylindrical member 22 may

- 11 -

be formed by machining a single piece of titanium to the desired shape. Alternatively, a phaco-emulsification needle in accordance with the present invention may be formed from stainless steel, a

5 suitably tough plastic composite, or a combination thereof. Likewise, projections 24 may be formed in any of a number of readily manufacturable configurations, for example, as circumferential channels with longitudinally-oriented communications, or even cylindrical nub-like shapes.

Referring now to FIGS. 7A through 7D, alternative designs of tip 18 of needle 20 are illustrated. FIG. 7A shows lumen 13 in the distal portion of needle 20 expanding to tip 18 in a funnel-like manner; FIG. 7B shows the lumen 13 having a curved horn-like shape as it expands to tip 18. FIGS. 7C and 7D illustrate alternative embodiments in which lumen 13 expands to tip 18 through a series of multi-chamber steps 13A-13B and 13A-13C. The foregoing lumen and tip configurations may be advantageously used with any of the phaco-emulsification needles of the present invention.

Referring now to FIGS. 8A and 8B, another alternative embodiment of the phaco-emulsification

25 needle of the present invention, needle 40, is described, again in which like numbers denote like parts. Needle 40 includes reduced-circumference portion 21 in mid-region 25. Flanges or projections 24 and cylindrical member 22 form a separate insert 41

30 which is disposed on the reduced-circumference portion 21 of needle 40.

Insert 41 may be formed of a soft plastic or elastomeric material, for example, silicone, and preferably is dimensioned so that gap 42 forms between the inner surface of cylindrical member 22 and the outer surface of reduced-circumference portion 21.

20

Cylindrical member 22 may also include a longitudinal slit that permits cylindrical member 22 to be easily installed over reduced-circumference portion 21.

Alternatively, cylindrical member 22 may be 5 dimensioned to slip over a standard phacoemulsification needle 10 as shown in FIG. 1, but may then require the use of a larger sleeve 17 and larger entry wound. When installed on the either reducedcircumference portion 21 of needle 40 or standard 10 needle 10, insert 41 is expected to provide many of the advantages described hereinabove with respect to the needle embodiments of FIGS. 2-6.

Applicant has performed some closed chamber experiments employing a silicone model "eye" used in 15 phaco-emulsification training workshops, in which the silicone "cornea" can be exchanged. In particular, applicant used a Series 10000 Master phacoemulsification system, available from Alcon Surgical, Fort Worth, Texas, to compare the cooling performance of a needle constructed in accordance with the embodiment of FIG. 2 to a standard Master phacoemulsification needle.

The experiments were conducted using with a power setting of 70 on the Master system, a vacuum setting of 100 mmHg, a bottle height of 65 cm, an irrigant flow rate 20 cc/min and an initial irrigant temperature of 25.6 °C. Varying the incision size from 2.75 mm to 4.1 mm in the silicone cornea (obtained using a keratome), the temperature of the sleeve at the 30 point of compression by the incision was measured with a thermocouple for both the standard needle and the needle of FIG. 2 after 15 seconds of operation. The results are shown in Table 1.

- 13 -

TABLE 1

	Incision Size (mm)	Sleeve Tempo Standard Needle	erature [°] C <u>FIG. 2 Needle</u>
	2.75	53	37
5	3.00	50	32
	3.25	47	32
	3.50	44	30
	4.10	33	28

As will be observed from Table 1, the sleeve 10 temperature was lower for the needle of FIG. 2 at all incision sizes and always remained below 40 °C. contrast, using the standard tip, the sleeve reached temperature levels exceeding fifty degrees -- a temperature at which thermal damage and collagen shrinkage would be expected to occur. 15

Applicant performed similar experiments in which the incision size was maintained at 3.00 mm and the flow rate was varied from 20 to 35 cc/min. the performance of neither the standard needle nor the 20 needle of FIG. 2 varied much with change in irrigant flow rate, the sleeve temperature for the needle of FIG. 2 was consistently about 20 °C lower than for the standard needle. In yet a third series of experiments, applicant kept the incision size at 3.00 mm and the flow rate constant at 20 cc/min and varied the irrigant bottle height from 65 to 75 cm. This also did not produce much an effect in the sleeve temperature for either needle, but again the sleeve temperature for the needle of FIG. 2 was consistently about 20 °C lower 30 than for the standard needle.

25

While preferred illustrative embodiments of the present invention are described above, it will be obvious to one skilled in the art that various changes and modifications may be made therein without departing from the invention and it is intended in the appended claims to cover all such changes and modifications which fall within scope of the invention.

PCT/AU95/00558

What Is Claimed Is:

1. A phaco-emulsification needle
comprising:

a shaft having a proximal end, a distal end, a mid-region, a first circumference, and a longitudinal lumen extending through the shaft from the proximal end to the distal end;

a hub disposed at the proximal end, the longitudinal lumen extending through the hub; and

a tip disposed at the distal end,

wherein the mid-region has a second circumference and a plurality of longitudinally-oriented outwardly extending projections disposed from the second circumference.

- 2. The phaco-emulsification needle as defined in claim 1, wherein the second circumference is different than the first circumference.
- 3. The phaco-emulsification needle as defined in claim 2, wherein the second circumference is smaller than the first circumference.
- 4. The phaco-emulsification needle as defined in claim 3, wherein the projections have an outer diameter, and the outer diameter of the projections is flush with the first circumference.
- 5. The phaco-emulsification needle as defined in claim 1, wherein the longitudinal lumen has a first cross-sectional area and, in the mid-region, the lumen has a second cross-sectional area smaller than the first cross-sectional area.

- 6. The phaco-emulsification needle as defined in claim 1, wherein the outwardly extending projections form a plurality of ribs.
- 7. The phaco-emulsification needle as defined in claim 6 wherein the ribs are hollow.
- 8. The phaco-emulsification needle as defined in claim 6, wherein the plurality of ribs are mutually parallel.
- 9. The phaco-emulsification needle as defined in claim 8, wherein the plurality of ribs spiral around the second circumference.
- 10. The phaco-emulsification needle as defined in claim 6, wherein the plurality of ribs is spaced apart equidistant around the second circumference.
- 11. The phaco-emulsification needle as defined in claim 6, wherein the plurality of ribs define a plurality of grooves in communication with one another.
- 12. The phaco-emulsification needle as defined in claim 1, wherein the plurality of outwardly extending projections extend radially outward from the second circumference.
- 13. The phaco-emulsification needle as defined in claim 1 wherein the shaft is cylindrical.
- 14. The phaco-emulsification needle as defined in claim 1 wherein the longitudinal lumen expands to the tip in a shape selected from the group

consisting of a funnel-shape, a horn-shape and a multichambered stepped-shape.

- 15. The phaco-emulsification needle as defined in claim 1 wherein the phaco-emulsification needle is machined from a single piece of titanium.
- 16. A phaco-emulsification needle
 comprising:
- a shaft having a proximal end, a distal end, a mid-region, an outer circumference and a longitudinal lumen extending through the shaft from the proximal end to the distal end;
- a hub disposed at the proximal end, the longitudinal lumen extending through the hub; and
 - a tip disposed at the distal end;

wherein the mid-region comprises a portion having a plurality of longitudinally-oriented grooves in the outer circumference of the shaft.

- 17. The phaco-emulsification needle as defined in claim 16, wherein the longitudinal lumen has a first cross-sectional area and, in the mid-region, the lumen has a second cross-sectional area smaller than the first cross-sectional area.
- 18. The phaco-emulsification needle as defined in claim 16, wherein the plurality of longitudinally extending grooves is spaced apart equidistant around the second circumference.

- 17 -

- 19. The phaco-emulsification needle as defined in claim 16, wherein the plurality of longitudinally extending grooves defines a plurality of longitudinally extending rib-like projections interposed between respective ones of the plurality of longitudinally extending grooves, at least some of the longitudinally extending rib-like projections being hollow.
- 20. The phaco-emulsification needle as defined in claim 16, wherein the plurality of longitudinally extending grooves are aligned in a mutually parallel relation.
- 21. The phaco-emulsification needle as defined in claim 20, wherein the plurality of longitudinally extending grooves spiral around the midregion.
- 22. The phaco-emulsification needle as defined in claim 16, wherein the plurality of longitudinally extending grooves are in communication with one another.
- 23. The phaco-emulsification needle as defined in claim 16 wherein the shaft is cylindrical.
- 24. The phaco-emulsification needle as defined in claim 16 wherein the phaco-emulsification needle is machined from a single piece of titanium.
- 25. The phaco-emulsification needle as defined in claim 16 wherein the longitudinal lumen expands to the tip in a shape selected from the group consisting of a funnel-shape, a horn-shape and a multichambered stepped-shape.

A phaco-emulsification needle comprising:

a shaft having a proximal end, a distal end, a first circumference, a mid-region having a second circumference, and a longitudinal lumen extending through the shaft from the proximal end to the distal end;

a hub disposed at the proximal end, the longitudinal lumen extending through the hub;

a tip disposed at the distal end; and

a hollow sleeve disposed on the mid-region, the hollow sleeve having an outer surface, a portion the hollow sleeve forming a plurality of longitudinally-oriented, outwardly extending projections disposed from the outer surface.

- The phaco-emulsification needle as 27. defined in claim 26, wherein the second circumference is smaller than the first circumference.
- The phaco-emulsification needle as 28. defined in claim 26, wherein the projections have an outer diameter, and the outer diameter of the projections is flush with the first circumference.
- The phaco-emulsification needle as defined in claim 26, wherein the longitudinal lumen has a first cross-sectional area and, in the mid-region, the lumen has a second cross-sectional area smaller than the first cross-sectional area.
- The phaco-emulsification needle as defined in claim 26, wherein the plurality of outwardly extending projections forms a plurality of ribs spaced apart equidistant around the outer surface.

- 19 -

- 31. The phaco-emulsification needle as defined in claim 30, wherein at least some of the plurality of ribs are hollow.
- 32. The phaco-emulsification needle as defined in claim 30, wherein the plurality of ribs extend radially outward from the outer diameter.
- 33. The phaco-emulsification needle as defined in claim 26 wherein the shaft is cylindrical.
- 34. The phaco-emulsification needle as defined in claim 26 wherein the hollow sleeve is formed from a soft plastic or elastomeric material.
- 35. The phaco-emulsification needle as defined in claim 26 wherein the longitudinal lumen expands to the tip in a shape selected from the group consisting of a funnel-shape, a horn-shape and a multichambered stepped-shape.

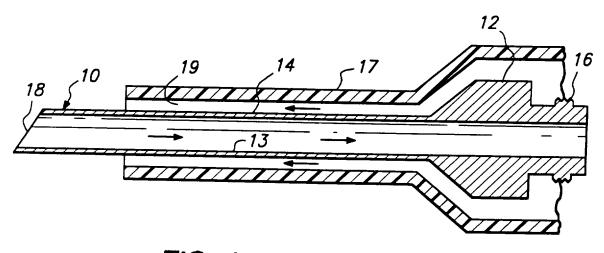
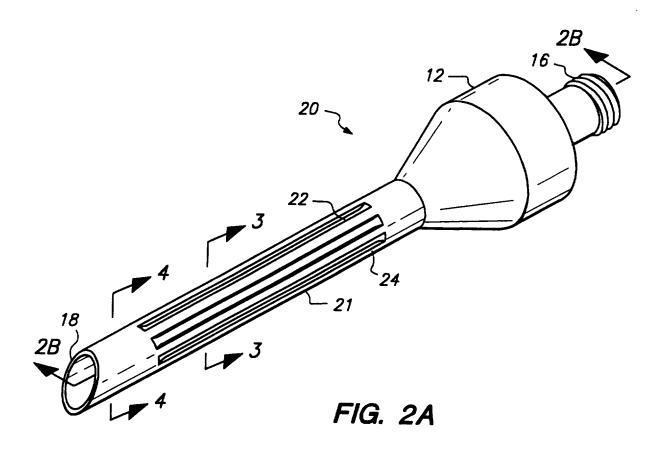


FIG. 1
PRIOR ART



SUBSTITUTE SHEET (RULE 26)

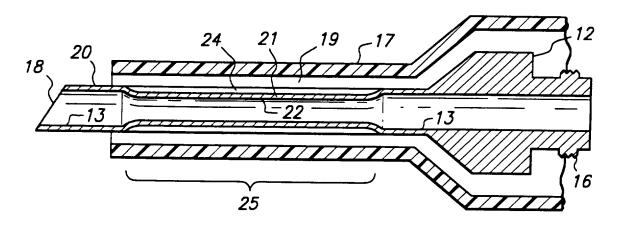


FIG. 2B

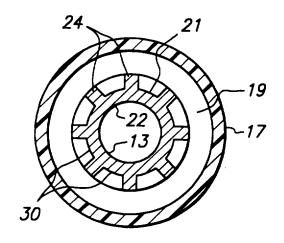


FIG. 3

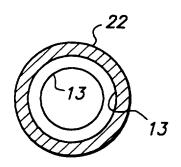
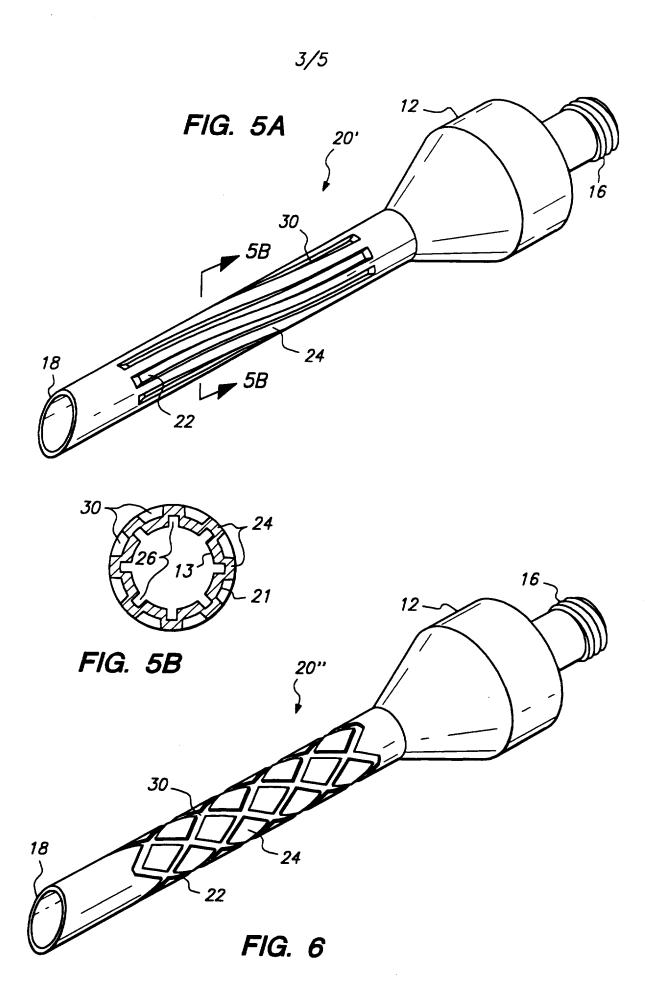


FIG. 4



SUBSTITUTE SHEET (RULE 26)

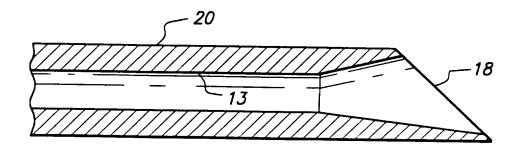


FIG. 7A

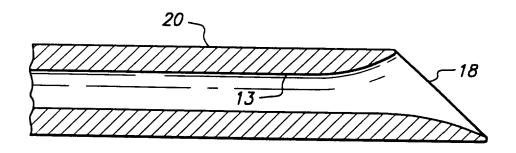


FIG. 7B

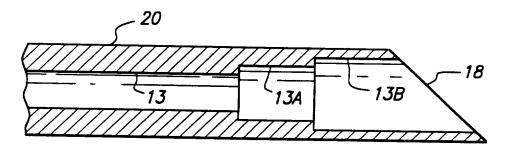


FIG. 7C

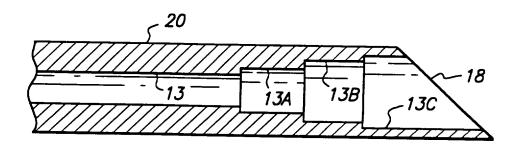
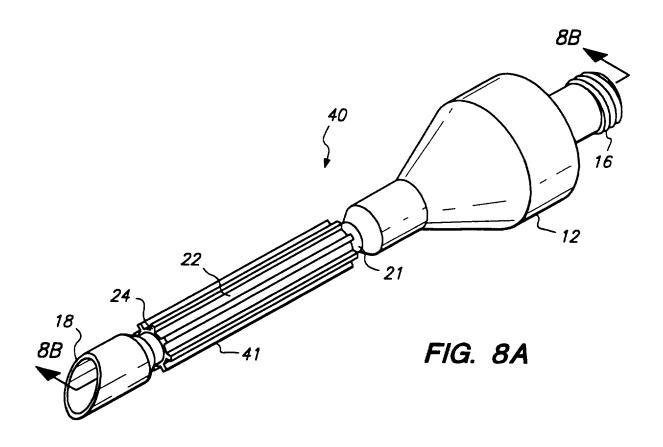


FIG. 7D

SUBSTITUTE SHEET (RULE 26)



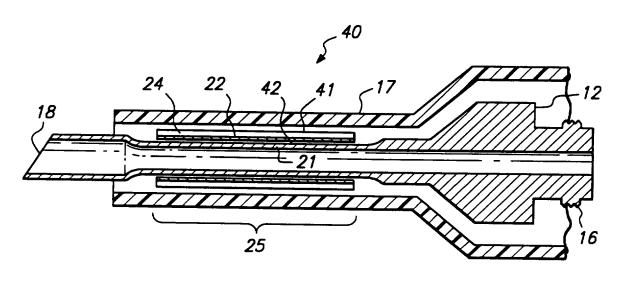


FIG. 8B

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AII 95/00558

A.	CLASSIFICATION OF SUBJECT MATTER	AU 33/00338
Int Cl ⁶ :	A61F 9/00	
According t	o International Patent Classification (IPC) or to both national classification and IPC	
В.	FIELDS SEARCHED	
Minimum doo	cumentation searched (classification system followed by classification symbols) A61F 9/IC; A61B 17/IC, A61B 19/IC and Keywords	
Documentation AU:	on searched other than minimum documentation to the extent that such documents are included in IPC as above	the fields searched
Electronic dat DERWENT	a base consulted during the international search (name of data base and, where practicable, search ultraso: and (needle or tip), (eye or lens or cataract) and removal (intraocul: or ophthalmic or removal)	ch terms used)
C.	DOCUMENTS CONSIDERED TO BE RELEVANT	
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Α	US 4689040 A (THOMPSON) 25 August 1987 See whole document	1-35
A	US 4808154 A (FREEMAN) 28 February 1989 See whole document	1-35
A	US 4816018 A (PARISI) 28 March 1989 See whole document	1-35
	Further documents are listed in the continuation of Box C See patent family annex	
'A" document con	l categories of cited documents: "IT" later document published after the in priority date and not in conflict with understand the principle or theory under	the application but cited to derlying the invention claimed invention cannot sidered to involve an taken alone claimed invention cannot step when the document is h documents, such n skilled in the art
	al completion of the international search Date of mailing of the international search	h report 1995
ame and mailing USTRALIAN I O BOX 200 ODEN ACT 2 USTRALIA	ng address of the ISA/AU NDUSTRIAL PROPERTY ORGANISATION 2606 Facsimile No.: (06) 285 3929 Talenhara No. (06) 285 3929	

INTERNATIONAL SEARCH REPORT

mernational Application No.

PCT/AU 95/00558

C (Continua	tion) DOCUMENTS CONSIDERED TO BE RELEVANT	
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4959049 A (SMIRMAUL) 25 September 1990 See whole document	1-35
A	US 5038756 A (KEPLEY) 13 August 1991 See whole document	1-35
A	US 5188589 A (WYPYCH) 23 February 1993 See whole document	1-35
A	AU 21228/92 A (ALCON SURGICAL INC) 23 March 1993 See whole document	1-35
A	US 5199943 A (WYPYCH) 6 April 1993 See whole document	1-35
A	EP 541249 A2 (SURGICAL DESIGN CORPORATION) 12 May 1993 See whole document	1-35
A	US 5286256 A (MACKOOL) 15 February 1994 See whole document	1-35
A	AU 59847/94 A (MACKOOL) 15 August 1994 See whole document	1-35

INTERNATIONALER RECHERCHENBERICHT

Information on patent family members

International Application No. PCT/AU 95/00558

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	4689040			· · · · · · · · · · · · · · · · · · ·			
US	4808154						
US	4816018						
US	4959049	wo	9103205			-	
US	5038756						
US	5188589	AU	26008/92	CA	2079396	EP	536965
		wo	9306799				
AU	21228/92	CA	2071760	EP	534593	wo	9305716
		US	5282786				
US	5199943	wo	9311724				
EP	541249	US	5242385				
US	5286256	AU	59847/94	CA	2152596	EP	676931
		FI	953223	NO	952612	wo	9415539
AU	59847	CA	2152596	EP	676931	FI	953223
		NO	952612				

END OF ANNEX